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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,932	11/03/2003	Michael Schink	104035.271139	4940

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/700,932	SCHINK ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-55* is/are pending in the application.

4a) Of the above claim(s) *30 and 40-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE and amendment filed 11/30/2006; and election and amendment filed 03/27/2007.

Claims 1-26 have been canceled, and claims 27-55 have been added.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/2006 has been entered.

Response to Election/Restrictions

2. Applicant's election with traverse of Group I, and species un-foamed polyurethane, claims 27-29, 31-39, in the reply filed on 03/27/2007 is acknowledged. The traversal is on the ground(s) that the Examiner has already examined the subject matter of all of the present independent claims 27, 40 and 45. Specifically, claim 27 corresponds generally to original claim 5. Claim 40 corresponds generally to original

claim 1. Claim 45 corresponds generally to original claim 17. Accordingly, the subject matter to be examined has remained the same and for this reason alone, there is no serious burden on the Examiner if restriction is not required. The Examiner appears to take the position that present dependent claim 29 justifies the requirement for restriction. However, claim 29 has been presented together with a Request for Continued Examination and the subject matter to be examined has not changed thereby. Regarding the election of species requirement, it is noted that original claim 5 recited both foamed and unfoamed polyurethane. Applicants argue that the classification of the inventions of Groups I, II and III in the same class and the same subclass is at least a strong indication that there is no undue burden on the Examiner.

This is not found persuasive because the original presented claims were all directed to one invention that does not required polyurethane in the generic claims 1 and 17. The newly added claim 27 requires polyurethane and is equivalent to original claim 5, and further limited the invention by specific polyurethane recited in claim 29. As currently presented, claims 27-39 are distinct from present claims 40 and 45 that do not require polyurethane. Initially, the examiner examined claims 1 and 17 because both have the same technical features, and upon filling the RCE the examiner could have prosecuted claims 40-55 filed with the request for RCE and withdrawn claims 27-39 as an election with original presentation. However, to be fair to applicants they were given the opportunity to prosecute the newly added invention presented by claim 29. The amendment filed 11/30/2007 presented claims directed to specific polyurethane recited by claim 29, claims 40 and 45 that did not require polyurethane. Regarding species

election, both species foamed and unfoamed were previously presented in a Markush group in one claim, and it was not required to search for both species, however, the amendment has recited each species in separate claim requiring the examiner to search for both species. Therefore, the prior art that anticipates claim 45 and 40 may not anticipate claim 27, and the prior art that anticipates foamed polyurethane may not anticipate unfoamed polyurethane creating burden on the patent examiner. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however, extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 30, 40-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/27/2007.

Claims 27-29, 31-39 are included in the prosecution.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on May 02, 2001. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 28 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have introduced new matter that is not described in the specification as originally filed. Regarding claim 28, the claim recites "the first side of the matrix substantially retains its original adhesive strength after application of the active ingredient". Nowhere in the original specification such limitation was found. Regarding claim 36, the limitation of "the matrix comprises from 2 % to 10 % by weight of active ingredient" was not found in the original specification. In page 17, line 22 applicant disclosed amount of "0.1 to 10%".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 27, 28, 31, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 212 681 ('681).

EP '681 disclosed drug-releasing system comprised of a drug dispensing polyurethane matrix (abstract). The drug present in amount of 1-10% by weight of the matrix (co1.4, lines 50-51). The drug is dissolved in the matrix that further comprises permeation enhancer (col.5, lines 7-12). The polyurethane comprises hexamethylene diisocyanate and polyetherpolyol (col.7, lines 38-45). The adhesive characteristics of polyurethane as claimed by claims 27 and 28 are inherent. The reference does not disclose the polyurethane is foamed, therefore, the reference implied that the polyurethane is unfoamed.

9. Claims 27, 28, 31, 36, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by 4,839,174 ('174).

US '174 disclosed transdermal drug delivery system comprising a polyurethane matrix layer containing 5-50% of active agent dispersed in the matrix in a liquid form (abstract; col.2, lines 55-58; co1.4, lines 9-10). The matrix has a thickness range from 50 to 800 micron (co1.6, lines 1-5). The adhesive characteristics of polyurethane as

claimed by claims 27 and 28 are inherent. The reference does not disclose the polyurethane is foamed, therefore, the reference implied that the polyurethane is unfoamed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of EP '681 or US '174, each in view of US 6,191,216 ('216).

The teachings of EP '681 and US '174 are discussed as set forth in this office action.

Although EP '681 disclosed polyurethane comprising hexamethylene diisocyanate and polyetherpolyol, however, the reference does not explicitly teach the specific polyetherpolyol as claimed by claim 29. US '174 disclosed polyurethane matrix, but it does not teach its specific polyurethane ingredients as claimed by claim 29.

US '216 teaches polyurethane gel composition that is preferred to use in medical applications because it is strongly self-adhesive and it is suitable for sticking to the skin in wound dressing (col.4, lines 45-57). The self-adhesive polyurethane gels comprises polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate (col.2, lines 3-13).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug as disclosed by any of EP '681 or US '174, and replace the polyurethane with the specific polyurethane gel disclosed by US '216 and comprising polyether polyols with 2 to 6 hydroxyl groups and having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate, motivated by the teaching of US '316 that such a polyurethane gel composition is preferred to use in medical applications because it is strongly self-adhesive and suitable for sticking to the skin, with reasonable expectation of having drug releasing system comprising drug in polyurethane gel matrix comprising polyether polyols with 2 to 6 hydroxyl groups and

having OH values of 20 to 112 and an ethylene oxide content of ≥ 10 wt. %, and hexamethylene diisocyanate that is strongly self-adhesive that sticks to the skin effectively.

13. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of EP '681 or US '174, each in view of US 6,399,092 ('092).

The teachings of EP '681 and US '174 are discussed as set forth in this office action.

However, the references do not teach that the polyurethane matrix comprises superabsorbent as claimed by claim 32.

US '092 teaches wound dressing superabsorbent polymer and active ingredient that when applied to the skin the superabsorbent absorbs fluid and slowly releases the active agent into the skin (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising drug in polyurethane matrix as disclosed by any of EP '681 or US '174, and further add superabsorbent to the drug containing matrix as disclosed by US '092, motivated by the teaching of US '092 that when superabsorbent is added to the drug containing matrix it absorbs fluid from the skin and slowly releases the active agent into the skin, with reasonable expectation of having drug releasing system comprising polyurethane matrix containing drug and superabsorbent that absorbs fluid from the skin and slowly releases the active agent into the skin, hence enhancing the drug release to the skin.

14. Claims 33, 35, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 5,866,157 ('157).

The teachings of EP '681 are discussed as set forth in this office action.

Although EP '681 suggested analgesics and anesthetics among other drugs suitable to be delivered in the polyurethane matrix, however, the reference does not specifically teach active agents recited by claim 33 or the essential oils claimed by claim 35. The reference does not teach the specific enhancers disclosed by claim 38 or the thickness of the matrix as claimed by claim 39.

US '157 teaches patch formulation for delivering active agent to the skin that has increase percutaneous absorption of the drugs with extremely reduced skin irritation (abstract). The formulation comprises permeation enhancers including isopropyl myristate and menthol, which is an essential oil (col.5, lines 11, 14). The active agents included lidocaine (col.3, line 33). The examples showed that the drug containing layer having thickness of 100 μm.

Therefore, US '157 showed that lidocaine is known to be delivered to the skin in skin patches, and one having ordinary skill in the art would have used lidocaine in the matrix disclosed y EP '681. The references also showed that such thickness of the drug containing layer as claimed has been used in the art.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug and permeation enhancer as disclosed by EP '681, and replace

the permeation enhancer with isopropyl myristate and menthol as disclosed by US '157, motivated by the teaching of US '157 that transdermal formulation comprising such enhancer has increase percutaneous absorption of the drugs with extremely reduced skin irritation, with reasonable expectation of having drug releasing system comprising polyurethane matrix comprising drug, myristate and menthol providing increased percutaneous absorption and extremely reduced skin irritation at the site of application.

15. Claims 33, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '174 in view of US '157.

The teachings of US '174 are discussed as set forth in this office action.

However, US '174 does not specifically teach active agents recited by claim 33 or the essential oils claimed by claim 35. The reference does not teach the specific enhancers disclosed by claim 38.

US '157 teaches patch formulation for delivering active agent to the skin that has increase percutaneous absorption of the drugs with extremely reduced skin irritation (abstract). The formulation comprises permeation enhancers including isopropyl myristate and menthol, which is an essential oil (col.5, lines 11, 14). The active agents included lidocaine (col.3, line 33).

Therefore, US '157 showed that lidocaine is known to be delivered to the skin in skin patches and one having ordinary skill in the art would have used lidocaine in the matrix disclosed y US '174.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide drug releasing system comprising polyurethane matrix comprising drug as disclosed by US '174, and further add permeation enhancer including isopropyl myristate and menthol as disclosed by US '157, motivated by the teaching of US '157 that transdermal formulation comprising such enhancers has increase percutaneous absorption of the drugs with extremely reduced skin irritation, with reasonable expectation of having drug releasing system comprising polyurethane matrix comprising drug, myristate and menthol that has increased percutaneous absorption and extremely reduced skin irritation at the site of application.

16. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of EP '681 or US '174, each in view of US 6,630,442 ('442).

The teachings of EP '681 and US '174 are discussed as set forth in this office action.

However, the references do not specifically teach dexpanthenol as an active agent as claimed by claims 33 and 34.

US '442 teaches composition comprises dexpanthenol that repairs and reduces skin damage because it is quick and deep penetrating moisturizer (abstract; col.23, lines 38-42).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polyurethane matrix drug comprising drug as disclosed by any of EP '681 or US '174, and replace the drug with dexpanthenol or

further add dexpanthenol to the matrix as disclosed by US '442, motivated by the teaching US '442 that dexpanthenol repairs and reduces skin damage because it is quick and deep penetrating moisturizer, with reasonable expectation of having polyurethane matrix comprising drug and/or dexpanthenol that repairs and reduces skin damage effectively.

17. Claim 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of EP '681 or US '174, each in view of EP 1 059 032 ('032).

The teachings of EP '681 and US '174 are discussed as set forth in this office action.

However, the references do not specifically teach essential oils as active ingredient as claimed by claims 33 and 35.

EP '032 teaches essential oils including menthol are preferred topical disinfectant because of the advantage of imparting pleasant odor to the disinfecting composition (paragraphs 0035, 0036).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polyurethane matrix comprising drug as disclosed by any of EP '681 or US '174, and replace the drug with essential oil including menthol as disclosed by EP '032, motivated by the teaching of EP '032 that essential oils including menthol are preferred topical disinfectant because of the advantage of imparting pleasant odor to the disinfecting composition, with reasonable expectation of having

polyurethane matrix comprising menthol that has disinfecting effect and further impart pleasant odor to the matrix.

Response to Arguments

18. Applicant's arguments filed 11/30/2006 have been fully considered but they are not persuasive. Applicants argue that EP '681 and US '174 do not teach the self adhesive matrix, and disclosed a pressure sensitive adhesive layer to attach the patch to the skin.

In response to this argument, applicants' attention is directed to the scope of the rejected claims that is matrix comprising polyurethane and active agent dissolved in the matrix. EP '681 teaches polyurethane absorbs water and dissolves the drug incorporated in the polyurethane (col.5, lines 40-46) leading to polyurethane matrix and dissolved drugs as instantly claimed. EP '681 teaches the same polyurethane comprising the same ingredient as claimed by applicants, therefore, the adhesive properties are inherent to the same polyurethane. US '174 teaches transdermal drug delivery system comprises polyurethane matrix and the active agent added in a liquid (col.3, line 21) leading to polyurethane matrix and liquid drugs as instantly claimed. Claim 27 does not teach any specific polyurethane, and the polyurethane disclosed by the US '174 reads on the claimed polyurethane, and inherently will have the same adhesive properties. The expression "comprising" of the claims' language permits the presence of other skin adhesive layers.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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IG

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